REMARKS

Claims 1 and 2 are pending in this application, claim 3 having been previously canceled without prejudice. No new matter has been added to the claims in this response.

I. Rejection Under 35 U.S.C. § 103(a)

Claims 1 and 2 stand rejected under 35 U.S.C. § 103(a) as obvious over Meheus et al., 1987, Postgraduate Med. J. 63(Supp 2):139-141 (hereafter, "Meheus") in view of Whalen et al., 1995, Ann. N.Y. Acad. Sci. 772:64-76 (hereafter, "Whalen") and Schirmbeck et al., 1995, J. Virol. 69(10):5929-34 (hereafter, "Schirmbeck"). The Examiner contends that Meheus describes the immunization of human infants 24 hours after birth with a protein vaccine, while Whalen and Schirmbeck disclose that a DNA vaccine may be used for immunizing mice. According to the Examiner, it would have been obvious to immunize newborn humans 24 hours after birth, as described by Meheus, with a DNA vaccine, as described by Whalen and Schirmbeck.

Applicant respectfully disagrees. To support an assertion of obviousness, the Examiner must show that "all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art." M.P.E.P § 2143. *See also, KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

The pending claims are directed to a method for immunizing an infant human against a target antigen, comprising inoculating the infant with a naked recombinant nucleic acid encoding a relevant epitope of the target antigen within the age of birth to one month. Additionally, the claims are also directed to a method for inducing a cytotoxic T cell response against a pathogen in an infant human, comprising inoculating the infant human with a naked recombinant nucleic acid encoding more than one relevant epitope of one or more target antigens associated with the pathogen within the age of birth to one month.

Applicant submits that the claims are not obvious over the cited references when considered separately or in combination because an artisan of ordinary skill, in view of the references, would have no reasonable expectation of successfully practicing the claimed invention. The Examiner relies on Meheus for the reference's alleged disclosure that a human

infant can be immunized within the age of birth to one month with a protein immunogen. For example, the Examiner states that "Meheus teaches that recombinant protein is . . . highly immunogenic in newborns . . . and vaccination results in newborns showed even at two months after third dose of vaccine." *See* the Office Action at page 3. According to the Examiner, vaccination resulted in 86% and 100% seroconversion in infants born to HBsAg-positive mothers (Group I) or women without HBV markers (Group II), respectively. However, the 86% and 100% seroconversion cited by the Examiner refer to seroconversion levels measured at four months after birth, following immunizations at 24 hours after birth, 1 month after birth and 2 months after birth. *See,* Meheus at page 140, first column, first full paragraph; and tables I and II. In contrast, the seroconversion rates measured at ***one*** month after birth, following a single immunization ***24 hours*** after birth, was only 40% and 46% for Groups I and II, respectively. Thus, Meheus discloses that humoral response in one month old human infants is low. *See,* Meheus at page 140, Tables I and II. As such, in view of Meheus, an artisan of ordinary skill would understand that even using a conventional protein vaccine, immunization within one month of birth gave unpredictable results. Accordingly, there would have been no reasonable expectation, when the invention was made, that an unconventional DNA vaccine, which, to be effective, requires at least expression of protein immunogen, would be successful within the same time period.

The Examiner relies on Whalen and Schirmbeck for the references' alleged disclosure that naked recombinant nucleic acid molecules can be used to immunize a subject. However, as noted by the Examiner, both references disclose the use of such nucleic acids for immunizing mice, and not a human, at ages older than the mouse equivalent of a one month old human infant. *See,* The Office Action at pages 5-7. Thus, in view of Meheus, Whalen and Schirmbeck's disclosures, an artisan of ordinary skill would have no reasonable motivation to immunize a human infant with a naked recombinant nucleic acid within the age of birth to one month as recited by the claims. As such, the references provide the artisan with no reasonable expectation of successfully practicing the claimed invention. In view of the foregoing, Applicant respectfully requests that the rejection be withdrawn.

II. Conclusion

In view of the above remarks, it is respectfully requested that the application be allowed and passed to issue. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below. Applicant believes that no fee in addition to the fees associated with the Request for Continued Examination and the Petition to extend time are due at this time. However, if any other fees are required, the Commissioner is authorized to charge such fees to Deposit Account No. 02-4377.

Respectfully submitted,
BAKER BOTTS L.L.P.

Dated: April 1, 2010

Dennis M. Bissonnette
Patent Registration No.: 61,910

Lisa B. Kole
Patent Registration No.: 35,225

30 Rockefeller Plaza
44th Floor
New York, NY 10112-4498
(212) 408-2500
(212) 408-2501 (fax)